

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): A freeze-dried formulation comprising:
a follicle-stimulating hormone (FSH) or a variant thereof; ~~as well as~~
a luteinising hormone (LH) or a variant thereof; ~~and, as well as~~
at least one surfactant selected from the group consisting of including Tween 20
(polyoxyethylene (20) sorbitan monolaurate), Tween 40 (polyoxyethylene (20) sorbitan
monopalmitate), and Tween 80 (polyoxyethylene (20) sorbitan monooleate).

Claim 2 (Original): The freeze dried formulation according to claim 1, wherein the
surfactant is Tween 20.

Claim 3 (Currently Amended): The freeze dried formulation according to ~~any of~~
~~claims 1 or 2~~ claim 1, wherein the follicle-stimulating hormone is a human
follicle-stimulating hormone and/or the luteinising hormone (LH) is a human luteinising
hormone (LH).

Claim 4 (Currently Amended): The freeze dried formulation according to claim 3,
wherein the follicle-stimulating hormone is a urinary human follicle-stimulating hormone
and/or the luteinising hormone (LH) is a urinary human luteinising hormone (LH).

Claim 5 (Currently Amended): The freeze dried formulation according to ~~any of~~
~~claims 1 to 3~~ claim 1, wherein the follicle-stimulating hormone is a recombinant human
follicle-stimulating hormone and/or the luteinising hormone (LH) is a recombinant human
luteinising hormone (LH).

Claim 6 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, wherein the follicle-stimulating hormone (FSH) is present at a concentration (w/w) of at or about 0.1 to 10 $\mu\text{g}/\text{mg}$ of the total formulation.

Claim 7 (Original): The freeze dried formulation according to claim 6, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 0.3 to 5 $\mu\text{g}/\text{mg}$ of the total formulation.

Claim 8 (Original): The freeze dried formulation according to claim 7, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 0.37 to 2 $\mu\text{g}/\text{mg}$ of the total formulation.

Claim 9 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 3 $\mu\text{g}/\text{mg}$ of the total formulation.

Claim 10 (Original): The freeze dried formulation according to claim 9, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 1 $\mu\text{g}/\text{mg}$ of the total formulation.

Claim 11 (Original): The freeze dried formulation according to claim 10, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 0.6 $\mu\text{g}/\text{mg}$ of the total formulation.

Claim 12 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, wherein ~~the a~~ ratio of FSH to LH is within ~~the a~~ range of at or about 6:1 to at or about 1:6.

Claim 13 (Currently Amended): The freeze dried formulation according to claim 12, wherein ~~the a~~ ratio of FSH to LH is within ~~the a~~ range of at or about 4:1 to at or about 1:2.

Claim 14 (Currently Amended): The freeze dried formulation according to claim 13, wherein ~~the a~~ ratio of FSH to LH is within ~~the a~~ range of at or about 3:1 to at or about 1:1.

Claim 15 (Currently Amended): The freeze dried formulation according to claim 14, wherein ~~the a~~ ratio of FSH to LH is within ~~the a~~ range of at or about 2:1 and 1:1.

Claim 16 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, further comprising sucrose.

Claim 17 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, further comprising methionine.

Claim 18 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, further comprising a phosphate buffer.

Claim 19 (Currently Amended): The freeze dried formulation according to ~~any of the preceding claims~~ claim 1, further comprising ~~the following ingredients~~: rFSH, rLH, Tween 20, sucrose, methionine, and a phosphate buffer.

Claim 20 (Currently Amended): The freeze dried formulation according to ~~any of claims 1 to 19, comprising claim 1, further comprising:~~

12.0 µg of recombinant FSH, 3.7 µg of recombinant LH, 30.0 mg of sucrose, 0.45 mg of NaH₂PO₄ H₂O, ~~mg~~ 1.11 mg of Na₂HPO₄ 2H₂O, 0.05 mg of Tween 20, and 0.1 mg of L-methionine.

Claim 21 (Currently Amended): An article of manufacture comprising:

a first container filled with a freeze dried formulation according to ~~any claims from 1 to 20~~ claim 1; and

a second container ~~comprising that comprises~~ a solvent for reconstitution.

Claim 22 (Currently Amended): An article of manufacture according to claim 21, ~~whereby~~ wherein the second container contains water for reconstitution.

Claim 23 (Currently Amended): A method for manufacturing a freeze dried formulation according to ~~any of claims 1 to 20~~ claim 1, comprising: ~~the step of~~ forming a mixture of FSH with ~~e-LH as well as a~~ and Tween 20, ~~and~~ subjecting the mixture to a ~~lyophilisation~~ lyophilization.